UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,229	04/08/2004	Tara Ziolo	5490E-000365	9402

27572 7590 01/09/2008
HARNESS, DICKEY & PIERCE, P.L.C.
P.O. BOX 828
BLOOMFIELD HILLS, MI 48303

EXAMINER	
CUMBERLEDGE, JERRY L	
ART UNIT	**PAPER NUMBER**
3733	
MAIL DATE	**DELIVERY MODE**
01/09/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/821,229	ZIOLO ET AL.	
	Examiner	Art Unit	
	Jerry Cumberledge	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 October 0207*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20,37-41,45 and 46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20,37-41,45 and 46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/05/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6, 8, 9, 11, 12, 15-21, 37-41, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Estes (US Pat. 5,578,034) in view of Ishida (US Pat. 5,158,409).

Estes discloses a bone fixation apparatus comprising: a bone fixation plate (Fig. 1, ref. 12) having a fixation hole (Fig. 1, ref. 18); and a modular bone fixation fastener (Fig. 1, ref. 14) received in the fixation hole (Fig. 1), the bone fixation fastener including a shaft member (Fig. 1, ref. 22) defining a longitudinal axis (Fig.1) and an expandable (column 5, lines 64-67) annular head member (Fig. 1, ref. 16) defining an internal surface (Fig. 1, surface of ref. 16 facing the shaft member).The fixation hole includes a countersunk portion (Fig. 1, portion near ref. 28) receiving at least a portion of the expandable head member of the bone fixation fastener. The inner surface of the fixation hole is spherical (Fig. 1, ref. 24) and engages a spherical outer surface of the head member (Fig. 1, ref. 21), such that the fixation fastener can be positioned at a plurality of angles relative to the plate before locking. The bone fixation plate is a spinal fixation plate for securing first and second vertebral bodies relative to one another. The bone fixation plate is a spinal fixation plate for securing at least three vertebral bodies relative

to one another. The bone fixation apparatus further comprises at least one aperture receiving an anchoring fastener (column 3, lines 28-32). The bone fixation apparatus further comprises at least another fixation hole receiving another modular fixation fastener (column 3, lines 28-32).

Estes discloses a bone fixation apparatus comprising: a bone fixation plate (Fig. 1, ref. 12) having a fixation hole (Fig. 1, ref. 18); and a modular bone fixation fastener (Fig. 1, ref. 14) received in the fixation hole (Fig. 1), the bone fixation fastener comprising: a shaft member (Fig. 1, ref. 22) having a first end (Fig. 1, end towards ref. 20). The inner surface of the fixation hole is spherical (Fig. 1, ref. 24) and engages a spherical outer surface of the head member (Fig. 1, ref. 21), such that the fixation fastener can be positioned at a plurality of angles relative to the fixation plate when the head member is not expanded (Fig. 1).

Estes discloses a bone fixation apparatus comprising: a bone fixation plate (Fig. 1, ref. 12) having a fixation hole (Fig. 1, ref. 18), the fixation hole having a first diameter in a plane generally parallel to an upper surface of the bone fixation plate (Fig. 1); and a modular bone fixation fastener (Fig. 1, ref. 14) received in the fixation hole (Fig. 1), the bone fixation fastener including a shaft member (Fig. 1, ref. 22) defining a shaft axis (Fig. 1, longitudinal axis) and an expandable (column 5, lines 64-67) annular head member (Fig. 1, ref. 16) carried by the shaft member (Fig. 1). The expandable head member has a generally spherical outer surface (Fig. 1). The fixation hole is generally spherical (Fig. 1).

Estes discloses a bone fixation apparatus comprising: a bone fixation plate (Fig. 1, ref. 12) having a fixation hole (Fig. 1, ref. 18); and a modular bone fixation fastener (Fig. 1, ref. 14) received in the fixation hole (Fig. 1), the bone fixation fastener comprising: a shaft member (Fig. 1, ref. 22) having a longitudinal axis (Fig. 1) and a first end (Fig. 1, end closer to ref. 20), and an expandable (column 5, lines 64-67) head member (Fig. 1, ref. 16).

Estes discloses that this mechanism is used to prevent fastener rotation (*i.e.* fastener backout) through the use of a shape memory alloy (column 3, lines 23-27).

Estes discloses the claimed invention except for the shaft member defining a circumferential outer cam at a first end, the outer cam in the form of a continuous curve of continuous slope and circumferentially variable radius in a plane perpendicular to the longitudinal axis, the internal surface of the head member defining a circumferential inner cam in the form of a continuous curve of continuous slope and circumferentially variable radius and devoid of kinks, the outer cam circumferentially mating with the inner cam of the head member in a position of cam alignment, such that upon rotation of the head member relative to the shaft member to a first position of cam misalignment, the head member radially expands to prevent back out of the shaft member relative to the bone fixation plate, the modular fixation fastener positionable at a plurality of angles relative to the fixation plate in the first position of cam misalignment through articulation of the expandable head member relative to the fixation hole. The outer cam and the inner cam each have at least one lobe, the lobe defined as a segment radially offset from the internal surface of the head member. The outer cam and the inner cam each

have a plurality of lobes, the lobes interconnected by variable radius curves. Each of the outer and inner cams includes three equidistant lobes, the lobes interconnected by variable radius curves. Upon rotation of the head member relative to the shaft member to a second position of cam misalignment the head member radially expands against an inner surface of the fixation hole to pressure-lock the fixation fastener and thereby prevent relative movement between the fixation fastener and the plate. The head member and the shaft member are cooperatively configured to provide a first mode of operation in which the head member is prevented from backing out relative to the plate and the fixation fastener is adjustable relative to the plate and a second mode of operation in which the head member is prevented from backing out relative to the plate and the fixation fastener is arrested relative to the plate. The first end defining a circumferential multi-radius continuously curved outer surface, the outer surface having continuous slope and defining a circumferential shaft cam lobe; and an expandable head member having an inner opening defining an internal circumferential surface in the form of a circumferentially multi-radius continuously curved inner surface, the inner surface having continuous slope and being devoid of kinks and defining a head cam lobe circumferentially mating with the shaft cam lobe in a position of cam alignment, such that upon rotation of the head member relative to the shaft member, the shaft cam lobe rotates out of alignment relative to the head cam lobe forcing the head member to expand radially to prevent back out of the shaft member relative to the bone fixation plate. The head member radially expands against an inner surface of the fixation hole to pressure-lock the fixation fastener and thereby prevent relative movement between the

fixation fastener and the plate. The inner head surface and the outer shaft surface each define a plurality of mating cam lobes, the lobes interconnected by variable radius curves. The head member and the fixation fastener are cooperatively configured to provide a first mode of operation in which the head member is prevented from backing out relative to the plate and the fixation fastener is adjustable relative to the plate and a second mode of operation in which the head member is prevented from backing out of relative to the plate and the fixation fastener is arrested relative to the plate. The expandable head member being expandable by rotation about the shaft axis relative to the shaft member from a first circumferential position in which the head member is not expanded and to a second circumferential position in which the head member is expanded, such that in the first position the expandable head member has a maximum diameter that is smaller than the first diameter of the fixation hole, and in the second position the expandable head member has a maximum diameter that is greater than the first diameter. The shaft member has a circumferential outer shaft cam mating with a corresponding circumferential internal head cam of the head member, such that in the first circumferential position the head and shaft cams are aligned and in the second circumferential position the head and shaft cams are misaligned, and wherein the each of the head and shaft cams is defined by a continuous curve of circumferentially variable radius and continuous slope. Each cam includes a plurality of lobes interconnected with variable-radius curves, and wherein in the second position the fastener is pressure locked against the fixation hole and thereby prevents relative movement between the fixation fastener and the plate. The first end defining a

continuous outer shaft cam curve on a plane perpendicular to the longitudinal axis, the outer shaft cam curve defining a plurality of cam lobes interconnected with curves of variable radius. An inner opening defining a continuous inner head cam curve, the inner head cam curve circumferentially mating and aligned with the outer shaft cam curve in an unexpanded configuration, the inner head cam curve circumferentially misaligned relative to the outer shaft cam curve in an expanded configuration. The shaft member is rotatable for moving the head member between the unexpanded and expanded configurations. The head member and the shaft member are cooperatively configured to provide a first mode of operation in which the shaft member is prevented from backing out relative to the plate and the fixation fastener is adjustably angled relative to the plate through articulation of the expandable head member relative to the fixation hole, and a second mode of operation in which the head member is prevented from backing out relative to the plate and the fixation fastener is locked at a fixed angle relative to the plate.

Ishida discloses a fastener locking mechanism comprising a fastener (Fig. 33, ref. 1c) and an expandable (column 9, lines 14-16) annular head member (Fig. 33, ref. 209). The fastener comprises an outer cam, the outer cam in the form of a continuous curve of continuous slope and circumferentially variable radius in a plane perpendicular to the longitudinal axis (Fig. 33, the outer surface of ref. 1c), the internal surface of the head member defining a circumferential inner cam (Fig. 33, the internal surface of ref. 209) in the form of a continuous curve of continuous slope (Fig. 33) and circumferentially variable radius (Fig. 33) and devoid of kinks (Fig. 33), the outer cam

circumferentially mating with the inner cam of the head member in a position of cam alignment, such that upon rotation of the head member relative to the shaft member to a position of cam misalignment, the head member radially expands to prevent back out of the shaft member relative to the bone fixation plate (column 9, lines 3-27). The outer cam and the inner cam each have at least one lobe (Fig. 1C, the wider portions of the respective cams). The lobes are offset from each other when the device is utilized (column 9, lines 3-27). The lobes interconnected by variable radius curves (Fig. 33). Each of the outer and inner cams includes three equidistant lobes (Fig. 33, column 9, lines 11-13).

Ishida discloses that this mechanism is used to prevent fastener rotation (column 1, lines 32-36).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have substituted the shape-memory alloy mechanism as taught by Estes with the cam mechanism as taught by Ishida to achieve the predictable result of preventing fastener rotation.

Claims 7 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Estes (US Pat. 5,578,034) in view of Ishida (US Pat. 5,158,409) in view of Eisermann (US Pat. 6,342,055).

Estes in view of Ishida disclose the claimed invention except for the bone fixation plate includes a viewing window.

Eisermann et al. disclose a bone fixation plate (Fig. 11, ref. 100) with windows (Fig. 11, ref. 108). The windows allow bone graft to grow through them and fuse with natural bone (column 8, lines 11-15). The windows can be considered to be "viewing windows", since one can see through to the other side of the plate die to their presence (Fig. 11).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the bone fixation plate of Estes in view of Ishida with the windows of Eisermann et al., which would allow bone graft to grow through them and fuse with natural bone (column 8, lines 11-15).

Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Estes (US Pat. 5,578,034) in view of Ishida (US Pat. 5,158,409) further in view of Bailey et al. (US Pat. 6,599,290 B2).

Estes in view of Ishida disclose the claimed invention except for an insertion and removal tool, the tool comprising a first driver attached to a handle, the driver adapted to engage the head member for rotation of the head member relative to the shaft member. The to comprises a second driver adapted to engage the shaft member for inserting and removing the shaft member to and from a bone portion when the fixation member is not locked.

Bailey et al. disclose a system comprising a bone plate (Fig. 1, ref. 12), fasteners (Fig. 1, ref. 14) and expandable annular locking members (column 2, lines 45-49). The system further comprises a tool having a first driver for engaging the head of a fastener

and a second portion for resiliently expanding the annular locking member (column 2, lines 45-49). This allows for the use of only one tool to engage both the head of a fastener and the annular locking member (column 2, lines 45-49).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the system as taught by Estes in view of Ishida with the driver as taught by Bailey et al., in order to allow for the use of only one tool to engage both the head of a fastener and the annular locking member (column 2, lines 45-49).

Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Estes (US Pat. 5,578,034) in view of Ishida (US Pat. 5,158,409) in view of Pohndorf et al. (US Pat. 5,904,683).

Estes in view of Ishida disclose the claimed invention except for the head member includes driver engagement formations for rotating the head member relative to the shaft.member for moving the head member between the unexpanded and expanded configurations.

Pohndorf et al. disclose a head member that has driver engagement formations for rotating the head member relative to the shaft member (Fig. 13, ref. 56), which are useful in that they allow a torque driving tool to engage directly with the head (column 5, lines 43-55).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the head member of Estes in view of Ishida

with driver engagement formations as taught by Pohndorf et al., in order to allow a torque driving tool to engage directly with the head (column 5, lines 43-55).

Response to Arguments

Applicant's arguments filed 10/25/200 have been fully considered but they are not persuasive.

With regard to Applicant's argument that the modular fixation fastener of Estes cannot angulate within the plate while in an unexpanded (cam-misaligned) state, the examiner respectfully disagrees. The annular head members disclosed by Estes, when unexpanded, have room in which they can be angulated (Fig. 1, ref. 16)(Fig. 6, ref. 170)(Fig. 7, ref. 220). The head members can be tilted relative to the plate by at least a few degrees (Fig. 1)(Fig. 6(Fig. 7).

With regard to claim 37, the device of Estes in view of Ishida would be capable of performing the second mode of operation, since once the locking member is expanded, the fixation fastener would be locked at a fixed angle (*i.e.* 90 degrees) relative to the plate.

In response to Applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a

reconstruction is proper. In re McLaughlin, 443 F.2d 1392; 170 USPQ 209 (CCPA 1971). Furthermore, the examiner notes that it would have been obvious to a person having ordinary skill in the art to consider locking mechanisms from other analogous arts (*e.g.* locking mechanisms used to lock bolts in place).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Cumberledge whose telephone number is (571) 272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JLC